IN THE CLAIMS

Please cancel claim 43.

1. (Currently Amended) A pharmaceutical formulation which comprises azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, and a steroid, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof~~, preferably the formulation being in a form suitable for nasal or ocular administration~~.

2. (Original) A pharmaceutical formulation according to claim1, wherein said azelastine is present as azelastine hydrochloride.

3. (Currently Amended) A formulation according to claim 1 ~~or 2~~, wherein the steroid is beclomethasone or a pharmaceutically acceptable ester thereof, mometasone or a pharmaceutically acceptable ester thereof, fluticasone or a pharmaceutically acceptable ester thereof, budesonide or cyclosenide, in any chiral form or mixture.

4. (Original) A formulation according to claim 3, wherein the steroid is beclomethasone propionate, mometasonefuroate, mometasone furoate monohydrate, fluticasone propionate or fluticasone valerate.

5. (Currently Amended) A formulation according to claim 1 ~~any of claims 1 to 4~~, which contains the steroid in an amount from about 50 micrograms/ml to about 5 mg/ml of the formulation.

6. (Currently Amended) A formulation according to claim 1 ~~any of claims 1 to 5~~, wherein the formulation has a particle size of less than about 10 μm~~, preferably less than 5μn~~.

7. (Currently Amended) A formulation according to claim 1 ~~any of claims 1 to 6~~, which is a suspension containing 0.0005 to 2% (weight/weight of the formulation) of azelastine or a pharmaceutically acceptable salt of azelastine, and from 0.5 to 1.5% (weight/weight of the formulation) of said steroid.

8. (Original) A formulation according to claim 7, which contains from 0.001 to 1% (weight/weight of the formulation) azelastine, or salt thereof, and from 0.5% to 1.5% (weight/weight of the formulation) steroid.

9. (Currently Amended) A formulation according to claim 1 ~~any of claims 1 to 8~~, which also contains a surfactant.

10. (Original) A formulation according to claim 9, wherein the surfactant comprises a polysorbate or poloxamer surfactant.

11. (Currently Amended) A formulation according to claim 9 ~~or 10~~, which contains from about 50 micrograms to about 1 milligram of surfactant per ml of the formulation.

12. (Currently Amended) A formulation according to claim 1 ~~any of claims 1 to 11~~, which also contains an isotonic agent.

13. (Original) A formulation according to claim 12, wherein the isotonic agent comprises sodium chloride, saccharose, glucose, glycerine, sorbitol or 1,2-propylene glycol.

14. (Currently Amended) A formulation according to claim 1 ~~any of claims 1 to 13~~, which also contains at least one additive selected from the group consisting of a buffer, a preservative, ~~and~~ a suspending agent and a ~~or~~ thickening agent.

15. (Original) A formulation according to claim 14, wherein said preservative is selected from edetic acid and its alkali salts, lower alkyl p-hydroxybenzoates, chlorhexidine,

phenyl mercury borate, or benzoic acid or a salt, a quaternary ammonium compound, or sorbic acid or a salt thereof.

16. (Currently Amended) A formulation according to claim 14 ~~or 15~~, wherein the suspending agent or thickening agent is selected from cellulose derivatives, gelatin, polyvinylpyrrolidone, tragacanth, ethoxose (water soluble binding and thickening agents on the basis of ethyl cellulose), alginic acid, polyvinyl alcohol, polyacrylic acid, or pectin.

17. (Currently Amended) A formulation according to claim 14 ~~any of claims 14,15 or 16~~, wherein the buffer comprises a citric acid-citrate buffer.

18. (Currently Amended) A formulation according to claim 14 ~~any of claims 14,15, 16 or 17~~, wherein the buffer maintains the pH of the aqueous phase at from 3 to 7, preferably 4.5 to about 6.5.

19. (Currently Amended) A formulation according to claim 1 ~~any of claims 1 to 18~~, which is an aqueous suspension or solution.

20. (Currently Amended) A formulation according to claim 1 ~~19~~, which is in the form of an aerosol, an ointment, eye drops, nasal drops, a nasal spray, ~~or~~ an inhalation solution and other forms suitable for nasal or ocular administration.

21. (Original) A formulation according to claim 20, which is in the form of nasal drops or nasal spray.

22. (Original) A formulation according to claim 20, which is in the form of an aerosol.

23. (Original) A pressure packing having a dosage or metering valve, which contains a formulation according to claim 22.

24. (Original) A MDI which includes a pressure packing according to claim 23.

25. (Currently Amended) A formulation according to claim 1 ~~any of claims 1 to 19~~, which is in the form of an insufflation powder.

26. (Currently Amended) A pharmaceutical product according to claim 1, comprising (i) azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, provided in an aerosol formulation preferably together with a propellant typically suitable for MDI delivery, and (ii) at least one steroid, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, provided in an aerosol formulation preferably together with a propellant typically suitable for MDI delivery, as a combined preparation for simultaneous, separate or sequential use in the treatment of conditions for which administration of one or more anti-histamine and/or one or more steroid is indicated.

27. (Currently Amended) An aerosol formulation preferably suitable for MDI delivery comprising the formulation of claim 1 ~~(i) azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, and (ii) at least one steroid, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof~~, together with a propellant.

28. (Original) A pharmaceutical product comprising (i) azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, provided as an insufflation powder, and (ii) at least one steroid, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, provided as an insufflation powder, as a combined preparation for simultaneous, separate or sequential use in the treatment of

conditions for which administration of one or more anti-histamine and/or one or more steroid is indicated.

29. (Original) An insufflation powder formulation comprising (i) azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, and (ii) at least one steroid, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, together with a pharmaceutically acceptable carrier or excipient therefor.

30. (Currently Amended) A pharmaceutical product comprising the formulation according to claim 1, wherein (i) azelastine, or a pharmaceutically acceptable salt thereof, and (ii) wherein at least one steroid is selected from the group consisting of beclomethasone, fluticasone, mometasone and pharmaceutically acceptable esters thereof, as a combined preparation with said azelastine for simultaneous, separate or sequential use in the treatment of conditions for which administration of one or more anti-histamine and/or one or more steroid is indicated.

31. (Currently Amended) A pharmaceutical formulation according to claim 1, wherein said ~~comprising (i) azelastine, or a pharmaceutically acceptable salt thereof, and (ii)~~ at least one steroid is selected from the group consisting of beclomethasone, fluticasone, mometasone and pharmaceutically acceptable esters thereof, together with a pharmaceutically acceptable carrier or excipient therefor.

32. (Currently Amended) The formulation of claim 3 in the form of a [[A]] nasal spray comprising azelastine, or a pharmaceutically acceptable salt thereof, together with mometasone either as mometasone free base or as mometasonefuroate, and a pharmaceutically acceptable carrier or excipient therefor.

33. (Currently Amended) A pharmaceutical product comprising the formulation according to claim 1, wherein said azelastine is azelastine hydrochloride and said steroid is beclomethasone dipropionate, as a combined preparation for simultaneous, separate or sequential use in the treatment of conditions for which administration of one or more anti-histamine and/or one or more steroid is indicated.

34. (Currently Amendedl) A pharmaceutical formulation according to claim 1, wherein said azelastine is ~~comprising~~ azelastine hydrochloride and said steroid is beclomethasone dipropionate, together with a pharmaceutically acceptable carrier or excipient therefor.

35. (Currently Amended) A pharmaceutical product comprising the pharmaceutical formulation of claim 1, wherein said azelastine is azelastine hydrochloride and said steroid is fluticasone propionate, as a combined preparation for simultaneous, separate or sequential use in the treatment of conditions for which administration of one or more anti-histamine and/or one or more steroid is indicated.

36. (Currently Amended) A pharmaceutical formulation according to claim 1, wherein said azelastine is ~~comprising~~ azelastine hydrochloride and said steroid is fluticasone propionate, together with a pharmaceutically acceptable carrier or excipient therefor.

37. (Currently Amended) A pharmaceutical product comprising the pharmaceutical formulation of claim 1, wherein said azelastine is azelastine hydrochloride and said steroid is fluticasone valerate, as a combined preparation for simultaneous, separate or sequential use in the treatment of conditions for which administration of one or more anti-histamine and/or one or more steroid is indicated.

38. (Currently Amended) A pharmaceutical formulation according to claim 1, wherein said azelastine is ~~comprising~~ azelastine hydrochloride and said steroid is fluticasone valerate, together with a pharmaceutically acceptable carrier or excipient therefor.

39. (Currently Amended) A pharmaceutical product comprising the pharmaceutical formulation of claim 1, wherein said steroid is azelastine hydrochloride and said steroid is mometasonefuroate, as a combined preparation for simultaneous, separate or sequential use in the treatment of conditions for which administration of one or more anti-histamineand/or one or more steroid is indicated.

40. (Currently Amended) A pharmaceutical formulation according to claim 1, wherein said azelastine is ~~comprising~~ azelastine hydrochloride and said steroid is mometasonefuroate, together with a pharmaceutically acceptable carrier or excipient therefor.

41. (Currently Amended) A pharmaceutical product comprising the pharmaceutical formulation of claim 1, wherein said azelastine is azelastine hydrochloride and said steroid is mometasonefuroate monohydrate, as a combined preparation for simultaneous, separate or sequential use in the treatment of conditions for which administration of one or more anti-histamine and/or one or more steroid is indicated.

42. (Currently Amended) A pharmaceutical formulation according to claim 1, wherein said azelastine is ~~comprising~~ azelastine hydrochloride and said steroid is mometasonefuroate monohydrate, together with a pharmaceutically acceptable carrier or excipient therefor.

43. Cancelled

44. (Currently Amended) A process of preparing a pharmaceutical product according to claim 26 ~~any of claims 26, 28, 30, 33, 35,37, 39 or 41~~, which process comprises providing (i) azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, and (ii) at least one steroid, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, as a combined preparation for simultaneous, separate or sequential use in the treatment of conditions for which administration of one or more antihistamine and/or one or more steroid is indicated.

45. (Currently Amended) A process of preparing a pharmaceutical formulation according to claim 1 ~~any of claims 1 to 22, 27, 29, 31, 32, 34, 36, 38, 40, 42 or 43~~, which process comprises admixing a pharmaceutically acceptable carrier or excipient with azelastine, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof, and at least one steroid, or a pharmaceutically acceptable salt, solvate or physiologically functional derivative thereof.

46. (Currently Amended) A method for the prophylaxis or treatment in a mammal, such as a human, of conditions for which administration of one or more anti-histamine and/or one or more steroid is indicated, which method comprises administration of a therapeutically effective amount of a pharmaceutical product according to claim 26 ~~any of claims 26, 28, 30, 33, 35, 37, 39 or 41~~, as a combined preparation for simultaneous, separate or sequential use in the treatment of such conditions.

47. (Currently Amended) A method for the prophylaxis or treatment in a mammal, such as a human, of conditions for which administration of one or more anti-histamine and/or one or more steroid is indicated, which method comprises administration of a therapeutically

effective amount of a pharmaceutical formulation according to claim 1 ~~any of claims 1 to 22, 27, 29, 31, 32, 34, 36, 38, 40, 42 or 43~~.

48. (Currently Amended) For use in the manufacture of a medicament for the prophylaxis or treatment in a mammal, such as a human, of conditions for which administration of one or more antihistamine and/or one or more steroid is indicated, a pharmaceutical product according to claim 26 ~~any of claims 26, 28, 30, 33, 35, 37, 39 or 41~~, as a combined preparation for simultaneous, separate or sequential use in the treatment of such conditions.

49. (Currently Amended) A method of treating irritation or disorders of the nose or eye which comprises applying either directly to nasal tissues or to the conjunctival sac of the eyes, as appropriate, a pharmaceutical product according to claim 26 ~~any of claims 26, 28, 30, 33, 35, 37, 39 or 41, or a pharmaceutical formulation according to any of claims 1 to 22, 27, 29, 31, 32, 34, 36, 38, 40, 42 or 43~~.

50. (Currently Amended) A method of treating airway disorders, comprising administering by nebulization to surfaces of the airway a treatment-effective amount of a product or formulation as defined in claim 1 ~~the preceding claims~~.

51. (New) A method of treating irritation or disorders of the nose or eye which comprises applying either directly to nasal tissues or to the conjunctival sac of the eyes, as appropriate, a pharmaceutical formulation of claim 1.

52. (New) A method of treating airway disorders, comprising administering by nebulization to surfaces of the airway a treatment-effective amount of a product according to claim 26.